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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,253	06/04/2007	Tobias Wunberg	584212009400	7825

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

NOTIFICATION DATE	DELIVERY MODE
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06/09/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeSD@mofo.com
PatentDocket@mofo.com
Drcaldwell@mofo.com

Office Action Summary	Application No. 10/579,253	Applicant(s) WUNBERG ET AL.	
	Examiner TAMTHOM N. TRUONG	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/4/07, 11/2/10</u> . | 6) <input type="checkbox"/> Other: ____. |

FIRST OFFICE ACTION

Claims 1-12 are pending.

Claim Objections

1. Claim 5-12 are objected to under 37 CFR 1.75 (c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n) In this case, claims 5-12 improperly depend from claim 3, which is itself a multiple dependent claim. Accordingly, the claims 5-12 have not been further treated on the merits.

Claim Rejections – 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. The limitation “solvates” has indefinite metes and bounds because the specification does not define said limitation in term of an appropriate solvent and its proportions.
- b. The term “characterized” renders claims 2-4 indefinite because it is not clear if the description following said term is a limitation or a preamble.

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- c. Claims 2 and 3 lack antecedent basis because they depend on claim 1, but recite the limitation of “alkyl” in the list of substituents on R⁹, which is not recited in claim 1.
- d. The term “controlling” is indefinite because it is not clear if it means “prophylaxis”, or “alleviating symptoms”, or “reducing viral growth”.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Scope of Enablement:** Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation and use of *salts*, does not reasonably provide enablement for the preparation and use of *solvates*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The quantity of experimentation necessary;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims: Claims 1 and its dependent claims recite the limitation of “solvates” or the “solvates of its salts” of the compound represented by formula (I). The term “solvates” covers various forms of the same compound at different proportions of solvents. Thus, the scope of “solvates” recited in claim 1 and its dependent claims are unduly broad.

The amount of direction or guidance presented: Although the specification lists possible salts, it does not describe “solvate” or provides guidance on what proportion of solvents to use for obtaining a “solvate”. Thus, the specification fails to provide sufficient enablement for making a “solvate” of the claimed compounds.

The state of the prior art: Although it is not unusual to expect a “solvate” of a compound, the process for selecting a solvent to make a solvate is not standard for all drugs since not all solvents can form solvates with all compounds. For the claimed compound, there is no reference teaching any possible solvate. Furthermore, the teaching of Vippagunta flatly states on page 18, section 3.4 the following:

“Predicting the formation of solvates or hydrates of a compound...is complex and difficult.”

Thus, the state of the prior art does not support the broad scope of the above claims.

The relative skill of those in the art: Even with the advanced training, the skilled clinician would have to engage in extensive research to select a “solvate” for each compound

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from the large Markush group of formula (I). Not only one has to determine an IC_{50} value, but also *in-vivo* activity to establish an LD_{50} , therapeutic index and active metabolites for each “solvate”. Given a large Markush group of formula (I), such a task would require a tremendous amount of effort, time and resource.

The predictability or unpredictability of the art & The quantity of experimentation necessary: The process of making a “solvate” is quite unpredictable because it is not possible to predict whether solid solutions will form and at what stoichiometry proportion (i.e, one, two, or half a molecule of solvent added per molecule of host) – see the following excerpt of

Vippagunta et. al. :

Each solid compound responds uniquely to the possible formation of solvates...and hence generalizations cannot be made for a series of related compounds. Certain molecular shapes and features favor the formation of crystals without solvent;...There may be too many possibilities so that no computer programs are currently available for predicting the crystal structures of ...solvates.

(Vippagunta et. al., Crystalline solids, *Advanced Drug Delivery Review*, 48(2001) 3-26)

Thus, with such a limited teaching from the specification and the art, the skilled chemist would have to engage in undue experimentation to make the hundreds of thousands of compounds and “solvates” of compounds represented by formula (I) recited in the above claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on Monday thru Friday (9:00-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*/Tamthom N. Truong/
Examiner, Art Unit 1624*

**/JAMES O. WILSON/
Supervisory Patent Examiner, Art Unit 1624**

6-9-10